

**Vermont Center on Tobacco Regulatory Science**

Low Nicotine Content Cigarettes in Vulnerable Populations: Currently Depressed (Project 3)

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**Abstract:**

Nearly half of the tobacco consumed in the United States is smoked by people with psychiatric illness. Reducing the nicotine content of cigarettes to a non-addictive level (i.e., < 0.2 mg nicotine) is an innovative regulatory strategy that could significantly reduce tobacco-related morbidity and mortality. However, an expert panel that evaluated the potential impact of this policy identified the possibility of unintended consequences for smokers with comorbid psychiatric illness as a key area of concern, as these smokers could also respond to reductions in the nicotine content of cigarettes with increases in psychiatric symptoms and with compensatory smoking. One important comorbid population to consider is smokers with current major depressive disorder (MDD), who comprise 20-30% of people with current nicotine dependence. Little is known about the effects a nicotine reduction policy might have on smokers with MDD, as to our knowledge no studies have reported the effects of very low nicotine content cigarettes on smoking rate, toxicant exposure, cigarette tolerability or depression severity in these smokers. This substantial gap in the literature will be addressed in the proposed project. In Study 1, participants will assess acute effects of four cigarette conditions of varying nicotine yield (0.83, 0.28, 0.10, 0.03 mg) on craving, nicotine withdrawal, and the degree to which the reduced-nicotine cigarettes substitute for normal-nicotine cigarettes when availability of the latter is constrained. In Study 2, after a 1-week, 2-session baseline assessment period, smokers with current MDD will be randomized to one of these same four cigarette conditions for a 12-week extended exposure phase. Over the baseline and extended-exposure phases, patterns of tobacco use, biomarkers of toxicant exposure, psychiatric symptoms, cognitive performance and smoking topography will be assessed. By examining both the potential positive and negative consequences of very low nicotine cigarette use in smokers with MDD, this study will examine whether a regulatory approach of reducing the nicotine content of cigarettes to a non-addictive level is a viable method of reducing smoking in this population.